MINUTES KENTUCKY BOARD OF PHARMACY

Marriott Downtown Louisville, Kentucky October 20, 2006

<u>CALL TO ORDER:</u> A regular meeting of the Kentucky Board of Pharmacy was held at the Marriott Downtown, Louisville, Kentucky. President Naseman called the meeting to order at 10:08 a.m.

Members present: Greg Naseman, Peter Orzali, Mike Leake, Catherine Shely, Sandy Simpson and Patricia Thornbury. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Steve Hart and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Ralph Bouvette, APSC; Chris Killmeier, Walgreens; Jan Gould, Kentucky Retail Federation; Dale Masten, National Association of Chain Drug Stores; and Anne Policastri, future Board Member. Melanie Curtis, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Thornbury, seconded by Mr. Leake and passed unanimously, the Minutes of September 13, 2006 were adopted as amended.

APPEARANCES: Jill Smith was sworn in by Melanie Curtis, Court Reporter. Ms. Smith appeared before the Board asking for permission to reciprocate her North Carolina pharmacist's license. She is under a North Carolina Agreed Order for diversion. Ms. Thornbury moved to allow Ms. Smith to reciprocate her license with an Agreed Order including stipulations as follows: 5 years probation beginning with the date of the North Carolina Agreed Order; maximum hours of work: 40 hrs/wk or 80 hrs/2wk, with exceptions to be approved by PRN Committee chairperson or Board President and notification provided to the Board; shall not serve as pharmacist-in-charge, but may petition the Board to serve as pharmacist-in-charge; may not have power of attorney during terms of probation; shall not be a preceptor; must provide copy of Agreed Order to all employers; must enter into an aftercare contract with PRN Committee, to include drug counselor if indicated; must submit signed release for Board access to all medical records; must attend NA/AA meetings no less than 3 times per week; must submit to the Board written monthly reports of all NA/AA meetings; must submit to random observed drug screens; shall be subject to quarterly inspections by the Board at all places of employment, with audits to be conducted if necessary, the cost of each inspection not to exceed \$500, may petition the Board to reduce the number of inspections two years from the date of the Agreed Order if all the conditions of the Agreed Order have been satisfied; perpetual inventory of Scheduled II and III drugs to be required at each place of employment; cannot own a pharmacy or be employed at a pharmacy owned by a family member; shall not ingest any mood altering substances whether legend or nonlegend medications including alcohol; notification to the Board within 10 days of all legend and nonlegend drugs prescribed/ingested; Board or Board President to approve all

pharmacies/worksites prior to employment; shall not dispense any drugs for herself or her family members; shall obtain all prescriptions and those of family members at pharmacy designated in writing to the Board; attendance at the University of Utah School on Alcoholism and Other Drug Dependencies, the South Eastern PRN meeting, or the CAPTASA conference within one year; provide the Board and PRN Committee with a written self-performance evaluation monthly; any violation of state and/or federal pharmacy or drug laws constitutes violation of Agreed Order and may result in an emergency suspension of pharmacist's license. The Agreed Order shall be reported to NABP. Mr. Orzali seconded, and the motion passed unanimously.

BOARD REPORTS: President.

- 1) President Naseman reported that the PRN Ad Hoc Committee has made significant progress.
- 2) President Naseman stated that the Executive Director Evaluation Committee has completed Mr. Burleson's evaluation. Mr. Orzali moved to approve the Executive Director's evaluation. The motion was seconded by Dr. Shely and passed unanimously.

Board Executive Director.

- 1) Each Board Member and staff was presented with a polo shirt embroidered with Kentucky Board of Pharmacy.
- 2) MARS reports included for August and September 2006.
- 3) Ms. Thornbury moved to approve the following trips for 2007: FARB- Executive Director, President, plus one other (3 people); APhA- Executive Director, President, plus one other (3 people); NABP Annual Meeting in Oregon- all Board Members and staff (12 people); NABP District Meeting in Florida- all Board Members and staff (12 people). The motion was seconded by Mr. Leake, and passed unanimously.
- **4)** Information from other states regarding background checks for pharmacists was presented to Board Members for their review. Further information will be presented and discussion continued at the December 13, 2006 Board Meeting.
- **5**) The new ARNP statutes are on the Board of Pharmacy website and will be published in the Kentucky Board of Pharmacy Newsletter.
- 6) The Board will have a continuing education program at the Kentucky Society of Health System Pharmacists meeting on November 10, 2006 from 3:20 p.m. to 4:10 p.m. at the Radisson in Lexington.
- 7) In the past the March Board Meeting was held at University of Kentucky and included University of Kentucky third year pharmacy students as part of the audience, however the University of Kentucky cannot host the meeting on March. Mr. Orzali moved to have the January 10, 2007 Board Meeting at University of Kentucky. Ms. Simpson seconded, and motion passed unanimously.

Board Staff. Steve Hart presented the new paperless inspection system, Sanswrite.

PRN Chairperson/Brian Fingerson. The CAPTASA meeting will be held January 26 and 27, 2007 at the Embassy Suites in Lexington, Kentucky.

CURRENT/PENDING CASES:

Ms. Simpson moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Thornbury seconded, and the motion passed unanimously.

Case No. 05-0106; Case No. 06-0003A&B&C; Case No. 06-0017; Case No. 06-0053A; Case No. 06-0054A; Case No. 06-0011; Case No. 06-0031B; Case No. 06-0040; Case No. 06-0042B; Case No. 06-0043A; Case No. 06-0046B; Case No. 06-0049; Case No. 06-0051; Case No. 06-0055A

CASE REVIEW COMMITTEE:

Mr. Orzali moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Shely seconded, and the motion passed unanimously.

Case No. 05-0069. REVISIT. Special limited medical gas pharmacy permit holder allegedly failed to renew the permit in a timely manner and continued to operate, allegedly closed a facility without proper notification to the Board office, and allegedly failed to have a consultant pharmacist. NEW INFORMATION: Agreed Order was not returned by permit holder, nor was the Agreed Order returned by the United States Postal Service as undeliverable. The Board Office does not have a current address to which to send the Agreed Order. Alleged violations of law: KRS 315.035, 201 KAR 2:106 Section 2(1)(c) and 201 KAR 2:225 Section 2(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 05-0104. REVISIT. Pharmacy intern has allegedly been charged with a Class D Felony, Wanton Endangerment in the first degree and a misdemeanor, Public Intoxication. NEW INFORMATION: Pharmacy intern has allegedly been dismissed from the University of Kentucky College of Pharmacy and pled guilty to Public Intoxication of a controlled substance, a misdemeanor. Alleged violations of law: 201 KAR 2:040 Section 5(1)(a)1 and KRS 315.121(1)(i). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0062. Pharmacist allegedly failed to complete 0.6 continuing education units in 2005. During a routine inspection it was found that the pharmacist had only completed 9 hours of continuing education for 2005. Alleged violations of law: KRS 315.065(2) and 201 KAR 2:015. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt

resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0069. Pharmacist allegedly diverted legend drugs, including controlled substances, from her place of employment. When the pharmacist was interviewed, the pharmacist admitted to taking the drugs and voluntarily surrendered her pharmacist's license. Alleged violations of law: KRS 217.181 and KRS 218A.1414. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0091. Pharmacist allegedly failed to complete 1.5 units of continuing education in 2005, she only completed 1.4. Alleged violations of law: KRS 315.065 and 215 KAR 2:015 Section 5 (1)(a). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0092. Special limited medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0093. Special limited medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0094. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0095. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0096. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0097. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0098. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0099. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1), (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0101. Pharmacist allegedly violated previous Agreed Order 05-0020. Pharmacist dispensed a prescription without proper authorization in 2003 and was required to obtain 6 hours of continuing education. The continuing education was to be completed within one year (July 6, 2006). On September 7, 2006 a letter was sent requesting the continuing education. The pharmacist forwarded to the Board Office certificates that were processed on September 13, 2006. Alleged violation of law: KRS

315.990(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0102. Pharmacist allegedly violated previous Agreed Order 05-0092. Pharmacist committed a medication error in 2005 and was required to obtain 6 hours of continuing education. The continuing education was to be completed within six months (September 8, 2006). On September 8, 2006 a letter was mailed requesting the continuing education. The pharmacist forwarded to the Board Office certificates that were processed on September 11, 2006. Alleged violation of law: KRS 315.990(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0105. Pharmacy permit holder failed to report change of PIC within 14 days of change. Notification was received from the PIC leaving; however no new PIC had been received as of September 28, 2006. Alleged violations of law: 201 KAR 2:205. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0106A. Special limited medical gas permit holder allegedly dispensed medicinal oxygen to patients after one year expiration of the prescription. Upon a routine inspection current prescriptions could not be located. Alleged violation of law: 201 KAR 2:185 Section 2(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0106B. Special limited medical gas consultant pharmacist allegedly allowed medicinal oxygen to be dispensed to patients after one year expiration of the prescription. Upon a routine inspection current prescriptions could not be located. Alleged violation of law: 201 KAR 2:185 Section 2(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

CORRESPONDENCE/COMMUNICATIONS:

Rite Aid requested an alternate system to having the pharmacist(s) sign a signature log. Ms. Thornbury moved to approve the request with the following wordings and conditions: it must be a daily signature log that a pharmacist signs at the end of his/her shift and it must state-"I attest to the fact that the information entered into the (computer) system this day, which bears my initials, has been reviewed by me and is correct as entered." Mr. Leake seconded and the motion passed unanimously.

Kroger requested an alternate system to having the pharmacist(s) sign a signature log. Dr. Shely moved to approve the request with the following wordings and conditions: it must be a daily signature log that a pharmacist signs at the end of his/her shift and it must state-"I attest to the fact that the information entered into the (computer) system this day, which bears my initials, has been reviewed by me and is correct as entered." Mr. Leake seconded and the motion passed unanimously.

Charles Tenhet requested dual PIC. Ms. Thornbury moved to accept this request, Ms. Simpson seconded, and the motion passed unanimously.

Lonnie Hubbard requested dual PIC. Ms. Thornbury moved to accept this request, Mr. Leake seconded, and the motion passed unanimously.

Jeffrey Lewis requested that his Kentucky pharmacist license be reinstated. Ms. Thornbury moved that NAPB be notified that a pharmacist that previously held a Kentucky pharmacist license that had lapsed shall be allowed to reciprocate. Mr. Leake seconded and there were six nays, the motion was defeated unanimously.

Mr. Orzali moved to accept Mr. Lewis's request to reactivate his Kentucky pharmacist's license upon successful completion the MPJE. Ms. Thornbury seconded and the motion passed unanimously.

George Bauer requested that his Kentucky pharmacist's license be reactivated. Ms. Thornbury moved to accept this request upon successful completion of the MPJE. Ms. Simpson seconded and the motion passed unanimously.

Martha King requested dual PIC. Ms. Thornbury moved to accept this request. Mr. Orzali seconded and the motion passed unanimously.

CONTINUING EDUCATION: Ms. Thornbury moved to accept the continuing education programs 06-52 through 06-53 as recommended. Mr. Leake seconded, and the motion passed unanimously.

NEW BUSINESS: University of Kentucky College of Pharmacy placed second at NACP.

Alan Grogan, President of Grogan's Healthcare Supply, requested that the Board list sterile water and sterile saline as "harmless drugs" and exempts them from the Board's oversight. Mr. Leake moved for the Executive Director to write a letter stating that we understand his concerns; however, the status of sterile water and sterile saline are set (Rx Only) by the FDA and that the FDA would be the proper authority to address this issue. Mr. Orzali seconded and the motion passed unanimously.

ADJOURNMENT: On motion by Dr. Shely, seconded by Ms. Simpson, and passed unanimously, President Naseman adjourned the meeting at 2:10 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on December 13, 2006 at the Board Office in Lexington, Kentucky.

Michael Burleson, Executive Director